Guidance for Industry and FDA:
FY 2007 MDUFMA Small Business Qualification Worksheet and Certification

Document issued on August 1, 2006

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

Contains Nonbinding Recommendations

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to —

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD, 20852

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance, contact —

Joseph V. Puleo
phone: (240) 276-3150 ext. 116
e-mail: joseph.puleo@fda.hhs.gov

Additional Copies

Additional copies are available from the Internet at: www.fda.gov/cdrh/mdufma/guidance

Copies are also available from the CDRH Facts-on-Demand system. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (2007) followed by the pound symbol (#). Follow the remaining voice prompts to complete your request.

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that the information requested in the guidance is not relevant to the decision-making process or that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at —

www.fda.gov/cdrh/resolvingdisputes/ombudsman.html

Contains Nonbinding Recommendations

Guidance for Industry and FDA:
FY 2007 MDUFMA Small Business Qualification Worksheet and Certification

Changes to the FY 2007 Guidance

(This edition makes no changes from the FY 2006 edition.)

Who can qualify as a small business under MDUFMA? For FY 2007, you can qualify for small business fee discounts under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) if you reported *gross receipts or sales* of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours and the *total* must be no more than $100 million. If your gross receipts or sales are no more than $30 million (including all of your affiliates, partners, and parent firms), you will also qualify for a waiver of the fee for your *first* (ever) premarket application (PMA, PDP, BLA, or Premarket Report).

You may use the *Small Business Qualification Worksheet* included with this guidance to help you determine whether you qualify as a MDUFMA small business. FDA does not require you to use this worksheet, and you will not submit the completed worksheet to FDA.

What are the benefits of qualifying as a MDUFMA small business? If you qualify as a MDUFMA small business, you will be eligible to pay reduced fees for your medical device applications that are subject to a user fee. You may also be able to obtain FDA review of your *first* premarket application (PMA, PDP, BLA, or Premarket Report) without paying any fee.

What are the standard and small business fees for FY 2007? The fees for FY 2007 are shown in the accompanying table. If your submission is subject to a fee, the law requires you to pay the standard fee unless FDA decides you qualify as a small business. If you qualify as a small business, you are eligible to pay a reduced fee. If you qualify as a small business with gross receipts or sales of no more than $30 million, no fee is required for your first (ever) premarket application.

How can I obtain an FDA decision that I am a small business for FY 2007? If you believe you qualify as a small business and want to pay reduced or waived fees, you should submit an *FY 2007 MDUFMA Small Business Qualification Certification* (Form FDA 3602 for FY 2007), your Federal income tax return for the most recent tax year, and the Federal income tax returns of each of your affiliates, partners, and parent firms for the most recent tax year. FDA will review your Certification and Federal income tax returns within 60 days

and will send you our decision that you are, or are not, a small business eligible for reduced or waived fees for submissions you make during FY 2007 (submissions received by FDA from October 1, 2006 through September 30, 2007). If we decide you are a small business, our decision letter will assign you a Small Business Decision number. You will need to provide this number to FDA each time your want to receive a small business fee discount for a premarket submission or when you want to obtain a fee waiver for your first premarket application.

What is the *most recent* tax year? The most recent tax year will be 2006, except —

- If you submit your FY 2007 MDUFMA Small Business Qualification *before* April 16, 2006 *and* you have not yet filed your return for 2006, you may use tax year 2005.
- If you submit your FY 2007 MDUFMA Small Business Qualification *after* April 16, 2007 *and* you have not yet filed your 2006 return because you obtained an extension, you may use tax year 2005.

When does my premarket application qualify for the "first premarket application" fee waiver? There are two important considerations here. First, your gross receipts or sales (including your affiliates, partners, and parent firms) must be no more than $30 million. This means that some firms that *do* qualify for small business fee discounts (because their gross receipts or sales are less than $100 million) will *not* qualify for the "first premarket application" fee waiver (because their gross receipts or sales are more than $30 million).

Second, the law requires you to count prior premarket applications made by your affiliates, partners, or parent firms when determining whether a premarket application is your "first." If you *or any affiliate, partner, or parent firm* previously submitted a premarket application, your application does *not* qualify for the fee waiver, and you must pay the fee that would normally apply.

FY 2007 Medical Device Review User Fees

Application	Standard Fee	Small Business
Premarket application (PMA, PDP, BLA)	$281,600	$107,008
Premarket report (PMR) for a reprocessed single-use device	$281,600	$107,008
First premarket application (PMA, PDP, BLA, or PMR) *by a small business* ($30 million threshold)	(Not applicable)	Fee is waived
Panel-track PMA supplement	$281,600	$107,008
BLA efficacy supplement	$281,600	$107,008
180-day PMA supplement	$60,554	$23,007
Real-time PMA supplement	$20,275	$7,705
510(k) premarket notification	$4,158	$3,326

Where can I obtain a copy of the *FY 2006 MDUFMA Small Business Qualification Certification* form? A copy of this form is included in this guidance. The form is not available as a separate document. You may print the pages that include the form, and then complete it by hand or by typewriter.

The PDF (portable document format) version of this guidance includes a version of the Certification which you may fill in and print using your PC. The PDF version of this guidance is available on the Internet at —

www.fda.gov/cdrh/mdufma/guidance/2007.pdf

The information you enter on the PDF version of the Certification form is not saved on your PC and is not sent to FDA. You will not be able to "retrieve" or "open" your completed Certification at a later time. After you complete the electronic version of the Certification, *you will need to print the form*, sign it, date it, and send in to FDA with your supporting Federal income tax returns.

Why does FDA require me to submit Federal (U.S.) income tax returns? Sections 738(d)(2)(B) and 738(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act require an applicant to pay the standard fees for its submissions *unless* it demonstrates it is a small business by submitting a copy of its most recent Federal income tax returns (and returns of all affiliates, partners, and parent firms). A consequence of this requirement is that you cannot qualify as a small business under MDUFMA if you have not submitted a Federal income tax return. Until you file a Federal income tax return, you can not qualify as a small business and, therefore, the law requires you to pay the standard fee for any medical device application you submit that is subject to a fee. FDA *cannot accept* a foreign tax return in place of a Federal (U.S.) income tax return.

My organization filed a Form 990, Return of Organization Exempt from Income Tax. Do I still need to qualify as a Small Business? Yes. The Federal Food, Drug, and Cosmetic Act does not exempt you from MDUFMA user fees or grant you automatic small business status simply because you are generally exempt from Federal income tax. You are subject to the same "gross receipts or sales" thresholds as other applicants. You should report your Total Revenue (line 12 of Form 990) as your "gross receipts or sales."

May I submit a foreign income tax return or other documentation to show I am a small business? No. Sections 738(d)(2)(B) and 738(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act specifically state than an applicant must support its claim that it qualifies as a small business "by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent firms . . . ." If you have not filed a Federal (U.S.) income tax return, you cannot qualify as a small business under MDUFMA.

Should a foreign applicant file a Federal (U.S.) income tax return in order to qualify as a small business under MDUFMA? FDA cannot provide advice concerning whether you should or should not file a Federal income tax return. Filing a Federal income tax return may have tax and other consequences beyond simply making you eligible as a small business under

MDUFMA. If you are in doubt as to whether it is advisable for you to file a Federal income tax return, you should consider consulting with qualified legal and tax professionals. Additional information on federal income taxation is available from the United States Internal Revenue Service (www.irs.gov).

What is the purpose of a Small Business Decision number? You will use your Small Business Decision number to demonstrate that you have qualified as a small business for FY 2007. For example, whenever you submit a Medical Device User Fee Cover Sheet (Form FDA 3601), you will provide your Small Business Decision number. This will allow FDA to quickly confirm that you are entitled to a reduced or waived fee.

When will my status as a small business begin? Your status as a small business will begin as of the date of FDA's decision letter finding that you qualify as a small business. FDA expects to make its decision within 60 days of receiving your Certification and supporting materials.

What fee must I pay if I submit an application before FDA determines that I qualify as a small business? The fee you must pay for an application is determined and fixed on the date FDA receives your application. *If you submit an application before FDA has determined you qualify as a small business, you must pay the standard (full) amount of any fee that applies*. FDA will not refund the difference between the standard (full) fee and the small business fee if you later qualify as a small business. *If you want to pay the small business fee for an application, do not submit it until you obtain your Small Business Decision number from FDA.*

When will my status as a small business expire? Your status as a small business *will expire September 30, 2007.*

Do I need to requalify as a small business for FY 2008 and future years? Yes.[1] You should submit a new MDUFMA Small Business Qualification Certification each year to qualify as a small business. This is because —

- Your "gross sales and receipts" will vary from one year to another.
- We will always need a copy of your most recent Federal income tax return.

[1] Although FDA's current authority to collect medical device user fees under MDUFMA expires October 1, 2007, FDA anticipates that Congress will reauthorize some form of medical device user fees for FY 2008 and later years. We will provide news on reauthorization on our Internet site (www.fda.gov/cdrh/mdufma) if and when legislation is enacted.

FDA will publish the qualification criteria for FY 2008 in the *Federal Register* as soon as possible in 2007, but not before August 1, 2007. We will announce full information on the criteria for FY 2008 on our Internet site at —

www.fda.gov/cdrh/mdufma

At the same time, FDA will also provide a new edition of this guidance (for FY 2008) on our Internet site.

Where do I send my completed *FY 2007 MDUFMA Small Business Qualification Certification* and supporting materials?

Send your completed Certification and copies of all of the Federal income tax returns that support your Certification to:

> FY 2007 MDUFMA Small Business Qualification (HFZ-222)
> Division of Small Manufacturers, International, and Consumer Assistance
> 1350 Piccard Dr.
> Rockville, MD 20850

Can I be certain FDA will protect my income tax returns and other financial information? Yes. Your income tax returns and other financial information are "confidential commercial information" and will not be released to the public.

What may happen if I submit a false certification? When you make your certification, you are explicitly certifying:

> ". . . to the best of my knowledge, the information I have provided in this Certification is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes."

This statement appears immediately above your signature.

A false certification is one where you report information that is *not true* (for example, your gross receipts or sales are actually higher than you state) or if you *fail to disclose* required information (for example, you fail to disclose the existence of a parent, partner, or affiliate).

If FDA determines you submitted a false certification, we may suspend your status as a Small Business, we may suspend the review of any application you submitted until you pay the full fee that applies to that type of application, we may seek payment of the unpaid portion of fees that should have been paid, we may take other legal actions that appear appropriate under the

circumstances, and you may be subject to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

If I have a question, who can I call? If you need additional information about becoming a MDUFMA small business, contact FDA's Division of Small Manufacturers, International, and Consumer Assistance at 800-638-2041 or 301-443-6597.

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FY 2007 MDUFMA Small Business Qualification Worksheet

1. Did you file a United States Federal income tax return for the most recent tax year?

   ☐ Yes — Go on to Question 2.
   ☐ No — *Stop*. You do not qualify as a small business for FY 2007.

What is the *most recent* tax year? The most recent tax year will be 2006, except —

- If you submit your FY 2007 MDUFMA Small Business Qualification *before* April 15, 2007 *and* you have not yet filed your return for 2006, you may use tax year 2005.
- If you submit your FY 2007 MDUFMA Small Business Qualification *after* April 15, 2007 *and* you have not yet filed your 2006 return because you obtained an extension, you may use tax year 2005.

2. Does the line for *gross receipts or sales* on your Federal income tax return for the most recent tax year show $100 million or less?

   ☐ Yes — Go on to Question 3.
   ☐ No — *Stop*. You do not qualify as a small business for FY 2007.

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Where do I find my *gross receipts or sales*? You reported your gross receipts or sales on your most recent Federal income tax return.

IRS Form	See Line Number	IRS Form	See Line Number
Schedule C (Form 1040)	1	Schedule C-EZ (Form 1040)	1
Form 1065	1a	Form 1065-B	1a
Form 1120	1a	Form 1120-F	Section II, 1a
Form 1120S	1a	Form 990	12
Any other form — *Please contact FDA.*			

3. Do you have any affiliates, parents, or partner firms?

   ☐ Yes — Go on to Question 4.
   ☐ No — *Stop*. You appear to qualify as a small business for FY 2007. To receive small business fees and waivers for your FY 2007 medical device submissions, please send the following documents to FDA:

      1. A complete, signed FY 2007 MDUFMA Small Business Certification, and
      2. A copy of your Federal income tax return for the most recent tax year.

What is an *affiliate*? This term is defined by § 737(8) of the Federal Food, Drug, and Cosmetic Act. *Affiliate* means a business entity that has a relationship with a second business entity if, directly or indirectly —

(a) one business entity controls, or has the power to control, the other business entity; or

(b) a third party controls, or has power to control, both of the business entities.

Send these materials to:

FY 2007 MDUFMA Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

FDA will review your materials within 60 days and will inform you of our decision that you are, or are not, a small business for FY 2007.

4. Do the amounts on the lines for *gross receipts or sales* on the Federal income tax return for the most recent tax year, for your firm and all of its affiliates, partners, and parent firms, *when added together*, total $100 million or less?

☐ Yes — *Stop*. You appear to qualify as a small business for FY 2007.

To receive small business fees and waivers for your FY 2007 medical device submissions, please send the following documents to FDA:

1. A complete, signed FY 2007 MDUFMA Small Business Qualification Certification, and
2. Copies of the Federal income tax returns of your firm and all of its affiliates, partners, and parent firms for the most recent tax year.

Send these materials to:

FY 2007 MDUFMA Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

FDA will review your materials within 60 days and will inform you of our decision that you are, or are not, a small business for FY 2007.

☐ No — You do not qualify as a small business for FY 2007.

FY 2007 MDUFMA Small Business Qualification Certification

Form Approved: January 9, 2004
Expiration Date: December 31, 2006
OMB Statement: See following page.

Section I — Information about Yourself

1. Name of entity claiming MDUFMA Small Business status:

2. Federal Employer Identification Number:

3. Address where entity is physically located:

4. Name of person making this Certification:

5. Your telephone number:
(_____) _____
Area Code Telephone Number

6. Your mailing address: ☐ Check (✓) if same as item 3.

7. Your e-mail address:

8. What is your relation to the entity claiming MDUFMA Small Business status?

9. Have you listed all of the entity's affiliates, partners, and parent firms on the second page (Section II) of this form?

Check (✓) *one* response: ☐ Yes ☐ The entity identified in item 1 has no affiliates, partners, or parent firms

10. Complete, sign, and date the following certification:

I certify that _____
Name of entity (must be identical to response to item 1)

(Check *one* response:)

☐ has no affiliates, partners, or parent firms,

☐ has only the affiliates, partners, and parent firms listed on the back (Section II) of this form,

and

(Check *one* response:)

☐ reported "gross receipts or sales" of no more than $100,000,000 on its most recent Federal income tax return. I have attached a true and accurate copy of the entity's most recent Federal income tax return.

☐ together with the affiliates, partners, and parent firms listed on the back of this form, reported total "gross receipts or sales" of no more than $100,000,000 on their Federal income tax returns. I have attached a true and accurate copy of the entity's most recent Federal income tax return, and a true and accurate copy of the most recent Federal income tax return of each of the entity's affiliates, partners, and parent firms.

I further certify that, to the best of my knowledge, the information I have provided in this Certification is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Signature of person making this Certification: _____

Date of this Certification: _____

Section II — Information about Your Affiliates, Partners, and Parent Firms

a. Name of Entity	b. Federal Employer Identification Number (EIN)	c. Relation to Entity Making this Certification (Check (✓) *One* Response)			d. Gross Receipts or Sales for Most Recent Tax Year
		Affiliate	Partner	Parent	
1		☐	☐	☐	$
2		☐	☐	☐	$
3		☐	☐	☐	$
4		☐	☐	☐	$
5		☐	☐	☐	$
6		☐	☐	☐	$
7		☐	☐	☐	$
8		☐	☐	☐	$
9		☐	☐	☐	$
10		☐	☐	☐	$
11		☐	☐	☐	$
12		☐	☐	☐	$
13 **Total Gross Receipts and Sales of All Affiliates, Partners, and Parent Firms** (Sum of lines 1 - 12)					$ $0.00
14 **Gross Receipts and Sales of the Entity Making this Certification**					$
15 **Total Gross Receipts and Sales Used to Determine Qualification as a MDUFMA Small Business** (Sum of lines 13 and 14)					$ $0.00

Mail your completed FY 2007 MDUFMA Small Business Qualification Certification and copies of your latest Federal income tax returns (including the latest returns of each of your affiliate, partner, and parent firms) to —

FY 2007 MDUFMA Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

(FDA Use Only)

Review: ☐ Information verified
☐ Information not verified
(Decision must be "Does not qualify")

Decision: ☐ Qualifies for Small Business fee discounts
☐ Qualifies for Small Business fee discounts and fee waiver for first premarket application

SBD07_____

☐ Does not qualify

OMB Statement. The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

and to

Department of Health and Human Services
Food and Drug Administration
CDRH, HFZ-20
2098 Gaither Road
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

Instructions for Completing Your FY 2007 MDUFMA Small Business Qualification Certification Form FDA 3602

You must complete and submit an FY 2007 MDUFMA Small Business Qualification Certification (Form FDA 3602) in order to be eligible for reduced or waived fees for medical device submissions you make during FY 2007 (submissions received by FDA from October 1, 2006 through September 30, 2007). You must also submit —

- a copy of your most recent Federal (U.S.) income tax return, *and*
- a copy of the most recent Federal income tax return of *each* of your affiliates, partners, or parent firms.

FDA will use these materials to decide whether you qualify as a "small business" within the meaning of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

Mail your FY 2007 MDUFMA Small Business Qualification Certification, and copies of the Federal income tax returns that support your Certification, to FDA at this address —

FY 2007 MDUFMA Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

For further assistance, please contact —

- Center for Devices and Radiological Health –
  Division of Small Manufacturers, International and Consumer Assistance: 800-638-2041 or 301-443-6597
- Center for Biologics Evaluation and Research –
  Regulatory Information Management Staff: 301-827-3503.

FIELD DEFINITIONS

Section I — Information about Yourself

1. Name of entity claiming MDUFMA Small Business status. Provide the full legal name of the entity –

- If the entity is a corporation, limited liability company, partnership, or other legal entity, the name used in its articles of incorporation, articles of organization, partnership registration, or other similar instrument filed with the State or other government under whose laws the firm was created.

- If the entity is a sole proprietorship (that is, the firm is owned entirely by one individual), the name used when filing Federal, State, or other taxes.

2. Federal Employer Identification Number. Your entity's Federal Employer Identification Number (EIN) was assigned to you by the U.S. Internal Revenue Service and uniquely identifies your business.

3. Address where entity is physically located. This is the address where your entity is physically located (the address you would give to a person who needed to travel directly to the entity's primary establishment).

4. Name of person making this Certification. This is the person who is responsible for the accuracy and completeness of the information provided in the Certification and who must sign the Certification (see item 9).

5. Your telephone number. This is the telephone number where FDA can reach you if we have a question concerning your FY 2007 MDUFMA Small Business Qualification Certification.

6. Your mailing address. This is the address to which you want FDA to send its decision letter informing you that you are, or are not, a small business. If your mailing address is the same as item 3, you can just check the box rather than repeating the information.

7. Your e-mail address. This is the e-mail address where FDA can reach you if we have a question concerning your FY 2007 MDUFMA Small Business Qualification Certification.

8. What is your relation to the entity claiming MDUFMA Small Business status? Briefly explain your position within the entity (*e.g.*, Chief Financial Officer; Vice President; Chief Counsel; or other relationship that gives you authority to provide an FY 2007 MDUFMA Small Business Qualification Certification on behalf of the entity).

9. Have you listed all of the entity's affiliates, partners, and parent firms on the back of this form? If you have any affiliates, partners, or parent firms, check the first box ("Yes") *and list them on the back of the form*. If the entity has no affiliates, partners, or parent firms, check the second box ("The entity has no affiliates, partners, or parent firms").

10. Complete, sign, and date the following certification. In this certification, you must provide the following information:

- The name of the entity that is claiming MDUFMA small business status. This must be identical to your response to item 1.

- Check *one* response to indicate whether the entity has any affiliates, partners, or parent firms —

- Check the first box if the entity has no affiliates, partners, or parent firms.
- Check the second box if the entity has only the affiliates, partners, or parent firms you listed on the back of the form.

- Check *one* response to indicate how the entity determined it met the requirement that it have "gross receipts or sales" of no more than $100 million —

  - Check the first box if the entity reported "gross receipts or sales" of no more than $100 million on its most recent Federal income tax return. Attach a true and accurate copy (a complete and unaltered copy) of the entity's most recent Federal (U.S.) income tax return. *FDA cannot accept a foreign tax return instead of a Federal (U.S.) income tax return.* If you cannot provide a Federal (U.S.) income tax return, you cannot qualify as a small business.

Where do I find my *gross receipts or sales*? You reported your gross receipts or sales on your most recent Federal income tax return.

IRS Form	See Line Number
Schedule C (Form 1040)	1
Schedule C-EZ (Form 1040)	1
Form 1065	1a
Form 1065-B	1a
Form 1120	1a
Form 1120-F	Section II, 1a
Form 1120S	1a
Form 990	12
Any other form	*Please contact FDA.*

What is the *most recent* tax year? The most recent tax year will be 2006, except —

- If you submit your FY 2007 MDUFMA Small Business Qualification *before* April 16, 2007 *and* you have not yet filed your return for 2006, you may use tax year 2005.
- If you submit your FY 2007 MDUFMA Small Business Qualification *after* April 16, 2007 *and* have not yet filed your 2006 return because you obtained an extension, you may use tax year 2005.

  - Check the second box if the entity *and* all of its affiliates, partners, or parent firms *together* reported "gross receipts or sales" of no more than $30 million on their most recent Federal income tax returns. Attach a true and accurate copy (a complete and unaltered copy) of the entity's most recent Federal income tax return *and* a true and accurate copy of each affiliate's, partner's, or parent firm's most recent Federal income tax return.

What is an *affiliate*? This term is defined by § 737(8) of the Federal Food, Drug, and Cosmetic Act. *Affiliate* means a business entity that has a relationship with a second business entity where, directly or indirectly —

(a) one business entity controls, or has the power to control, the other business entity; or

(b) a third party controls, or has power to control, both of the business entities.

- The person identified in item 4 ("Name of person making this Certification") must sign the Certification.

- Date the Certification (this is the date you signed the Certification).

Section II — Information about Your Affiliates, Partners, and Parent Firms

You must provide certain information about each of your affiliate, partner, or parent firms. The back of the form provides space for listing up to 12 affiliate, partner, or parent firms; if you have more than 12 affiliate, partner, or parent firms, you may provide the additional information on the back of one or more additional copies of the form (you do not need to complete the front of those additional forms).

Lines 1 through 12 —

List each affiliate, partner, or parent firm on a separate line. For each, provide the following information —

a. Name of Entity. Provide the full legal name of the affiliate, partner, or parent firm –

- if the entity is a corporation, limited liability company, partnership, or other legal entity, provide the name used in its articles of incorporation, articles of organization, partnership registration, or other similar instrument filed with the State or other government under whose laws the firm was created.

- If the entity is a sole proprietorship (that is, the firm is owned by an individual), provide the name used when filing Federal, State, or other taxes.

b. Federal Employer Identification Number (EIN). This number was assigned to the affiliate, partner, or parent firm by the U.S. Internal Revenue Service and uniquely identifies each business.

c. Relation to Entity Making this Certification. Check *one* response (put a ✓ in the appropriate column) to indicate whether the entity you are identifying is an *Affiliate*, a *Partner*, or a *Parent firm*.

d. Gross Receipts or Sales for Most Recent Tax Year.

Copy this number from the Federal income tax return for the affiliate, partner, or parent firm. See the instruction for item 9 to learn where you will find this information on a return.

Line 13 — Total Gross Receipts and Sales of All Affiliates, Partners, and Parent Firms. This is the sum of the gross receipts or sales shown in lines 1 through 12.

Line 14 — Gross Receipts and Sales of the Entity Making this Certification. This is the gross receipts or sales of the entity identified in item 1.

Line 15 — Total Gross Receipts and Sales Used to Determine Qualification as a MDUFMA Small Business. This is the sum of lines 13 and 14. To qualify as a MDUFMA small business fee discounts for FY 2007, this sum must be *no more than* $100 million.